

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

UNITED STATES OF AMERICA	§	
<i>ex rel.</i> John King & Tammy	§	CIVIL ACTION NO. 06-2662
Drummond, and John King &	§	
Tammy Drummond	§	
individually, et al.	§	
Plaintiffs,	§	
	§	
v.	§	
SOLVAY S.A., et al.	§	
	§	
Defendants.	§	

**RELATORS' MOTION TO EXCLUDE THE EXPERT TESTIMONY OF
RICHARD A. MORTIMER AND BRIEF IN SUPPORT**

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I. NATURE AND STAGE OF THE PROCEEDING

Pursuant to Court's Scheduling Order, as amended most recently on February 3, 2015 (Dkt. 383), discovery has closed. This motion to exclude the expert testimony of Dr. Richard A. Mortimer ("Dr. Mortimer") is filed pursuant to the May 15, 2015 deadline as amended on February 3, 2015. Solvay designated Dr. Mortimer as an expert on March 12 in response to the report offered by Relators' expert Dr. Meredith Rosenthal. Dr. Mortimer was deposed on April 10, 2015.

II. STATEMENT OF ISSUES & STANDARD OF REVIEW

Whether this Court should exclude the testimony of Dr. Mortimer as to the following topics:

- (1) Impact on sales of off-label promotions;
- (2) Epidemiological observations such as prevalence of hypogonadism and hypogonadism as an underdiagnosed condition;
- (3) Medical or clinical opinions such as the identification of "unmet needs" for medical treatment; and
- (4) Dr. Mortimer's legal opinions regarding *Bornstein* considerations, what constitutes a false claim, and the substance of state prior authorization policies and regulations.

The Fifth Circuit reviews a district court's decision to exclude expert witness testimony under an abuse of discretion standard, and the ruling "will not be disturbed on appeal unless it is manifestly erroneous." *United States v. Wen Chyu Liu*, 716 F.3d 159, 167 (5th Cir. 2013) cert. denied, 134 S. Ct. 1011, 187 L. Ed. 2d 858 (2014) (citing *United States v. Valencia*, 600 F.3d 389, 423 (5th Cir. 2010)).

III. SUMMARY OF THE ARGUMENT

Economist Richard A. Mortimer, an expert witness for Defendant Solvay Pharmaceuticals, Inc. (Solvay), offers opinions on a variety of topics, including of course

economics, but spanning epidemiology, prevalence, rate of diagnosis, and the supposed lack of effect of all off-label promotion. Dr. Mortimer is not qualified to offer opinions on subject other than economics, and as a result such opinions should be struck. Further, even within the subject of economics, Dr. Mortimer must satisfy *Daubert* standards for offering any opinion. As discussed below, Dr. Mortimer failed to do so for a number of opinions. As a result, pursuant to Federal Rule of Evidence 104(a) and 702, Relators John King and Tammy Drummond move to exclude Dr. Mortimer's testimony, regarding the following matters in this case:

- (1) Impact on sales of off-label promotions, given his arbitrary exclusion of evidence and failure to engage in his own analysis;
- (2) Epidemiological observations such as prevalence of hypogonadism and hypogonadism as an underdiagnosed condition, given his lack of qualifications;
- (3) Medical or clinical opinions such as the identification of "unmet needs" for medical treatment, given his lack of qualifications; and
- (4) Legal opinions regarding *Bornstein* considerations, what constitutes a false claim, and the substance of state prior authorization policies and regulations.

Dr. Mortimer's methodology and failure to undertake an independent analysis render unreliable his methodology underlying his opinions about the impact of marketing on the sales of the drugs at issue. Dr. Mortimer is an economist, and is not qualified to testify on items 2, 3, and 4. In addition, the basis and methodology of Dr. Mortimer with respect to these issues is not reliable. Finally, the opinions referenced in item 4 include improper legal evidence.

IV. STANDARD OF LAW

Federal Rule of Evidence 702 governs the admissibility of expert testimony. Fed. R. Civ. P. 702. The expert must testify to knowledge that will assist the trier of fact to understand or determine a fact in issue. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591 (1993). Although the *Daubert* case involved a scientific expert, the United States Supreme Court later

expanded the *Daubert* factors to apply in cases involving non-scientific experts. *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S.137 (1999).

In determining whether an expert's testimony complies with the requirements of Fed. Rule Evid. 702, the trial court, acting as a "gatekeeper," is charged with the responsibility to exclude unreliable scientific evidence. *See Daubert*, 509 U.S. at 591. The "reliable principles and methods" prong of Rule 702 analysis requires the Court to look to other factors in order to fulfill its designated "gatekeeping" role, including:

- 1) whether a theory or technique has been or can be tested;
- 2) whether the theory or technique has been subjected to peer review and publication;
- 3) the technique's known or potential rate of error and the existence and maintenance of standards controlling the technique's operation; and
- 4) whether a particular technique or theory has gained general acceptance in the relevant scientific community

See e.g. In re: Fosamax Products Liability Litig., No. 06 MD 1789 (JFK), 2013 US Dist. LEXIS at *21-22 (S.D.N.Y. Jan. 7, 2013) (citing *United States v. Williams*, 506 F.3d 151, 160 (2d Cir. 2007) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593-94,113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993))). The purpose of analyzing proposed expert testimony in light of Rule 702 and the *Daubert* reliability factors is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999).

Under *Daubert* the district court is to make a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at

592–93, 113 S.Ct. 2786. Among the factors to consider is whether the ““expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute.”” *Id.* at 591, 113 S.Ct. 2786 (quoting *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir.1985)). The Court referred to this requirement as “fit,” meaning that the expert testimony must not only be based on reliable science but must also “fit” the particular facts of the case. *See id.* In the Fifth Circuit, the party seeking to admit the expert testimony must demonstrate that (1) the expert is qualified, (2) the evidence is relevant to the suit, and (3) the evidence is sufficiently reliable. See *Watkins v. Telsmith, Inc.*, 121 F.3d 984, 988-89 (5th Cir. 1997). The party seeking to admit the expert testimony must provide “objective, independent validation of the expert’s methodology” and cannot rely on the “expert’s assurances that he has utilized generally accepted scientific methodology.” *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir. 1998) (citing *Daubert*). With respect to the matters challenged in this motion, Dr. Mortimer’s opinions fail to meet the standards established by *Daubert* and the Fifth Circuit for the admissibility of expert testimony. Dr. Mortimer’s testimony should therefore be excluded.

V. ARGUMENTS & AUTHORITIES

A. Dr. Mortimer’s Qualifications are Limited to his Training as an Economist

1. Dr. Mortimer’s Area of Expertise is Economics

[REDACTED]

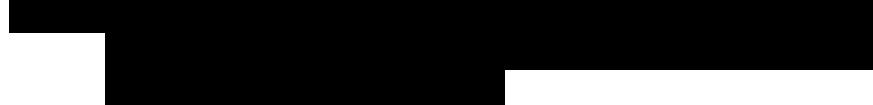
[REDACTED]

[REDACTED]

[REDACTED]

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2. Dr. Mortimer Admitted that He Had No Clinical Expertise and that He Did Not Consult Anyone with Clinical Expertise



[REDACTED]

[REDACTED]

[REDACTED]

B. Dr. Mortimer's Testimony Regarding Impact on Sales of Off-Label Promotions is *Ipse Dixit* and Therefore Inadmissible

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] This testimony must be excluded, however, because Dr. Mortimer failed to identify, let alone apply, a methodology nor did he identify any factual bases for reaching his opinion. In recent years the Supreme Court has put renewed emphasis on the importance of the “fit” of an expert's opinion to the data or facts in the case:

[C]onclusions and methodology are not entirely distinct from one another.... [N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytic gap between the data and the opinion proffered.

Concord Boat Corp. v. Brunswick Corp., 207 F.3d 1039, 1055 (8th Cir. 2000) (quoting *General Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997) and citing *Jaurequi v. Carter Mfg. Co.*, 173 F.3d 1076, 1082 n. 3 (8th Cir. 1999)). A court must focus on the “reasonableness of using such an approach, along with [the expert's] particular method of analyzing the data thereby obtained, to draw a conclusion regarding *the particular matter to which the expert testimony was directly relevant.*” *Concord*, 207 F.3d at 1055 (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 154, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999) (emphasis in original)). That is simply not the case here.

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This is a problem: when Dr. Mortimer makes the leap from criticizing Dr. Rosenthal's analysis to making his own conclusions of any kind about the facts of this case, he must support his own opinions with independent analysis. Apparently unwilling to delve into such analysis, he cannot utter *ipse dixit* opinions without running afoul of *Daubert* and its progeny. In fact, Dr. Mortimer has never undertaken the kind of analysis

It is black letter law that a district court “must assess whether the methodology used by the proposed expert is valid and whether it was properly applied.” *Kammerer v. Wyeth*, 2011 237757, at *1 (D. Neb. Nov. 1, 2011) (citing *In re Prempro Prods. Liab. Litig. (Scroggin)*, 586 F.3d 547, 565 (8th Cir. 2009)). This assessment has two prongs, both of which Dr. Mortimer fails. First, as discussed above, Dr. Mortimer should have applied a valid methodology—*no methodology* cannot be valid. In *MGM Well Services, Inc. v. Mega Lift Sys.*, LLC, CIV.A. H-05-1634, 2007 WL 150606, at *1 (S.D. Tex. Jan. 16, 2007), a lawyer with an electrical engineering background was excluded from testifying as to the technical issues encompassed in the patent dispute, because (1) he failed to perform his own calculations, but opined that MGM’s calculations were incorrect because the defendant’s president, told him so; and (2) he did not review data from testing that was allegedly performed on Mega Lift’s plunger system, testifying in his deposition that he was not aware of the test and had not seen any of the results, rendering his opinion *ipse dixit*. See also *Orthoflex, Inc. v. ThermoTek, Inc.*, 986 F.Supp.2d 776, 798 (N.D.Tex. 2013), “Although in forming an independent opinion an expert can rely on information provided by a party’s attorney, an expert cannot forgo his own independent analysis and rely exclusively on what an interested party tells him.”; *Stinson Air Ctr., LLC v. XL Specialty Ins. Co.*, Civ. No. SA-03-CA-61-FB, 2005 WL 5979095, at *3 (W.D.Tex. July 8, 2005) (also excluding expert opinion based upon representations of interested party without independent analysis). Because Dr. Mortimer did not just critique Dr. Rosenthal’s analysis, [REDACTED] [REDACTED], he was required to support it with his own independent review and analysis.

Second, as discussed below, Dr. Mortimer has to properly apply the methodology. In order to properly apply a methodology, courts will look at whether the “expert sufficiently

connected the proposed testimony with the facts of the case.” *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686-697 (8th Cir. 2001). Dr. Mortimer failed to do so.



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Dr. Mortimer cannot, under *Daubert*, base his analysis on no methodology and no evidence. Yet, because this is precisely what Dr. Mortimer did, his opinion that [REDACTED] [REDACTED] is mere *ipse dixit*, which is precisely what the Court is empowered and designed to keep out through its gatekeeping function.

C. Dr. Mortimer's Opinions Regarding Epidemiological Observations [REDACTED]

Should be Excluded

In responding to Dr. Rosenthal's report and testimony, Dr. Mortimer, though an economist like Dr. Rosenthal, offered his own various observations and opinions about the [REDACTED] based on his own interpretation of epidemiological literature as well as sources that cite no data whatsoever:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

In fact, Dr. Mortimer offered his own calculation of [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Dr. Mortimer's testimony and opinion [REDACTED]

[REDACTED] should be struck because (1) Dr. Mortimer is not qualified to render opinions on this issue and (2) there was no reliable basis for these opinions.

1. Dr. Mortimer is Not Qualified to Assess Epidemiological Evidence

[REDACTED] requires understanding of both basic epidemiology and clinical understanding as to [REDACTED]; Dr. Mortimer, while undoubtedly a competent economist, has expertise in neither of these subjects. While he is free to assume a fact for the purposes of his analysis in this case, his own observations regarding the landscape of epidemiologic evidence of prevalence is not helpful to the jury. Case law is clear that the expert must be qualified to give the opinions offered. This correlation between qualifications and opinion is narrowly construed. For example, in *Seatrax, Inc. v. Sonbeck Intern., Inc.*, 200 F.3d 358 (5th Cir. 2000), the Fifth Circuit held that an expert witness's 15 years of experience in the crane industry did not qualify him to opine about profit margins in that same industry. *Id.* at 371-372. Similarly, in *Smith v. Goodyear Tire & Rubber Co.*, 495 F.3d 224 (5th Cir. 2007), the Fifth Circuit upheld the exclusion of a polymer scientist's opinion regarding the cause of a burst tire, because the expert had not worked in the tire industry in any capacity and had never testified as a tire expert. *Id.* at 226-227. If such experts, whose expertise is actually related to the opinions offered, could not offer those opinions, it is axiomatic

that Dr. Mortimer—an economist—cannot offer opinions on the rate of diagnosis of hypogonadism.

2. Unsurprisingly, Dr. Mortimer's Assessment of ██████████ is Based on Unreliable Methodology

Examining Dr. Mortimer's analysis more closely reveals the perils of allowing an economist to opine on such questions. Dr. Mortimer states that he offers no opinion as to whether

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Dr. Mortimer also makes unacknowledged assumptions, such as relying on a [REDACTED]
[REDACTED]
[REDACTED] even though the [REDACTED]

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A further problem arises in asking this economist to consider

and whether he considers

1. **What is the primary purpose of the proposed legislation?**

When asked about this, Dr. Mortimer responded that it was his opinion that [REDACTED]

[REDACTED] Dr. Mortimer is neither a physician nor an epidemiologist. As discussed, the Fifth Circuit—like all other federal courts—requires an expert to be qualified to offer an opinion about the particular topic and facts underlying the opinion. The evidence shows that Dr. Mortimer was not qualified to render an opinion [REDACTED] and that the bases for his opinions were not reliable. Dr. Mortimer’s opinions about [REDACTED] [REDACTED] should be excluded at trial.

D. Dr. Mortimer Lacks Qualifications to Offer Medical or Clinical Opinions Such as the Identification of “Unmet Needs” for Medical Treatment

The Court should also exclude any testimony in which Dr. Mortimer offers any clinical or medical opinions, as an economist simply does not by virtue of such degree have expertise in this field. Dr. Mortimer nevertheless offers [REDACTED]

[REDACTED] While he is qualified to discuss such putative factors (using reliable methodology), Dr. Mortimer is in no position to search the medical literature [REDACTED]

[REDACTED] He is not qualified, therefore, to opine to the jury that based on his independent interpretation of medical literature:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

These clinical/medical observations make for unreliable methodology as well. A central fallacy of the claims about [REDACTED] is that Dr. Mortimer [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

E. Dr. Mortimer's Legal Opinions Should be Excluded

The testimony of Dr. Mortimer should be struck to the extent he attempts to render or support any legal opinion. He has acknowledged that he is not holding himself out as a legal expert (Tr. 46:18-21), and expert opinions interpreting the law are inappropriate in any case. Under Rule 704(a), “[t]estimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact.” Fed.R.Evid. 704(a); *see United States v. Moore*, 997 F.2d 55, 57–58 (5th Cir.1993) (discussing Rule 704(a)). That rule, however, does not allow a witness to give legal conclusions. *Owen v. Kerr-McGee Corp.*, 698 F.2d 236, 240 (5th Cir.1983); *United States v. Fogg*, 652 F.2d 551, 557 (5th Cir.1981), *cert. denied*, 456 U.S. 905, 102 S.Ct. 1751, 72 L.Ed.2d 162 (1982); *United States v. Milton*, 555 F.2d 1198, 1203 (5th Cir.1977). *See* McCormick, Evidence § 12 (1972).

1. *Bornstein* Considerations As They Relate to Rebates

For instance, Dr. Mortimer offers an opinion concerning

[REDACTED]. Dr. Mortimer was never qualified to testify as a legal expert; and to the extent he opines on or attempts to influence [REDACTED], such an opinion would be improper. Furthermore, any opinion as to [REDACTED]

issue the final determination must be left to the Court.

In the *Bornstein* case the United States Supreme Court held: "We agree that the Government's damages should be doubled before any compensatory payments are deducted,

because that method of computation most faithfully conforms to the language and purpose of the Act." *Bornstein*, 423 U.S. at 314, 96 S.Ct. at 530. The Court went on to state:

For these reasons we hold that, in computing the double damages authorized by the Act, the Government's actual damages are to be doubled before any subtractions are made for compensatory payments previously received by the Government from any source. This method of computation, which maximizes the deterrent impact of the double-damages provision and fixes the relative rights and liabilities of the respective parties with maximum precision, best comports in our view with the language and purpose of the Act.

Bornstein, 423 U.S. at 316-17, 96 S.Ct. at 531. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Dr. Mortimer's opinions do not meet the requirements for expert testimony established by the United State Supreme Court and the Fifth Circuit. Relators therefore respectfully ask the Court to exclude Dr. Mortimer's opinions on [REDACTED]

2. What Constitutes a False Claim

At various points in his report, Dr. Mortimer [REDACTED]

[REDACTED] While explicit assumptions about the law are permissible and pose no *Daubert* or related concerns, Dr. Mortimer's testimony during his deposition threatened to venture into his own interpretation of the Court's rulings [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

opinions amount to legal conclusions—and erroneous ones. Relators therefore ask that any opinion by Dr. Mortimer regarding what constitutes a false claim be excluded.

3. State Prior Authorization Policies and Regulations

At pages 72-73 of his report, Dr. Mortimer opines on [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] Moreover, in no way does it assist the jury to hear this economist explain how such statutes or regulations may work. To the extent that Dr. Mortimer wishes to offer opinions at trial with regard to these policies or regulations, his testimony should be excluded.

VI. CONCLUSION

For the reasons provided above, Relators John King and Tammy Drummond respectfully request that this Court not permit Dr. Mortimer to testify regarding the following:

- (1) Impact on sales of off-label promotions;
- (2) Epidemiological observations such as prevalence of hypogonadism and hypogonadism as an underdiagnosed condition;
- (3) Medical or clinical opinions such as the identification of “unmet needs” for medical treatment; and
- (4) Legal opinions regarding *Bornstein* considerations, what constitutes a false claim, and the substance of state prior authorization policies and regulations.

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